IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patricia SALVATI et al. Docket No: Applicant: 373987-004US (396982)

Serial No.: 10/541,195 Confirmation No.: 7746

Filed: June 30, 2005 1617 Group Art Unit:

For: ALPHA-AMINOAMIDE Examiner: Sahar JAVANMARD

> DERIVATIVES USEFUL AS ANTIMIGRAINE AGENTS

APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST FOR RECONSIDERATION UNDER 37 CFR § 1.705(b)

Mail Stop: Issue Fee Commissioner for Patents P.O. Box 1450 Alexandría, VA 22313-1450

Sir:

This is a request for reconsideration of the patent term adjustment of 259 days set forth in the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) that was attached to the Notice of Allowance mailed on November 2, 2009 for the above-referenced patent application. It is respectfully requested that applicants be granted a minimum patent term adjustment of 697 days, which may be extended based on the actual date of issuance of a patent for the above-referenced application.

The issue fee is being paid concurrently herewith.

Applicants submit herewith a "Statement Under 37 CFR § 1.702(b)(2)".

In accordance with 37 CFR §1.705(b)(1), please charge the fee set forth in 37 CFR §1.18(e) (\$200.00) to Dechert LLP Deposit Account No. 50-2778 (373987-004US (396982)).

Applicants kindly request grant of this application.

Respectfully submitted,

Date: January 15, 2010

Stefan M. Miller Reg. No. 57,623

DECHERT LLP Customer No. 37509

Tel: 212.698.3627 Fax: 212,698,3599

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DERIVATIVES USEFUL AS ANTIMIGRAINE AGENTS

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Mail Stop: Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This statement is respectfully submitted in support of the "Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR § 1.705(b)" for the above-referenced patent application. In view of the following, it is respectfully requested that applicants be granted a minimum patent term adjustment of 697 days.

The patent term adjustment on the Determination of Patent Term Adjustment Under 35 U.S.C. §154(b) ("PTAS Sheet") that was attached to the Notice of Allowance and which is submitted herewith as Exhibit A, is 259 days. That determination projected that the patent would issue on May 11, 2010 (the Tuesday before the date that is 28 weeks after the November 2, 2009 mailing date of that notice). A copy of the Office's calculation for the 259 days, printed from PAIR, is submitted herewith as Exhibit B.

This determination of 259 days is in error: as further elaborated below, the Office (i) failed to take certain action within the time frame specified in 37 CFR § 1.702(a) and (ii) failed to issue a patent within three years of the actual filing date of the above-referenced application in accordance with 37 CFR § 1.702(b). See Wyeth v. Kappos, No. 2009-1120 (Fed. Cir. Jan 7, 2010). What follows is a statement of the facts involved specifying the correct patent term adjustment and the basis for the adjustment under 37 CFR § 1.702. The statement includes the relevant dates as specified in 37 CFR § 1.703(a)—(e) for which adjustment is sought, and the adjustment as specified in 37 CFR § 1.703(f) to which the patent is entitled, and any circumstances during the prosecution of the application resulting in

the patent that constitutes a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 CFR § 1.704. The application is not subject to a terminal disclaimer.

A. 14 Month Delay under 37 CFR §§ 1.702(a) and 1.703(a)

Pursuant to 37 CFR §§ 1.702(a)(1) and 1.703(a)(1), applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than 14 months after the date the application fulfilled the requirements of 35 U.S.C. § 371 (i.e., June 30, 2005) (hereinafter "14 Month Delay"). A request for early processing under 35 U.S.C. § 371(f) was filed for the present application on June 30, 2005. Applicants <u>agree</u> with the Office's calculation shown in Exhibit B that the 14 Month Delay is <u>418 days</u>.

The Office failed to mail an action under 35 U.S.C. § 132 until October 22, 2007. Applicants are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date on which the above-referenced application fulfilled the requirements of 35 U.S.C. § 371, *i.e.*, August 31, 2006, and ending on the date of mailing of an action under 35 U.S.C. §132, *i.e.*, October 22, 2007. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 418 days.

B. 3 Year Delay under 37 CFR §§ 1.702(b) and 1.703(b)

Pursuant to 37 CFR §§ 1.702(b) and 1.703(b), applicants are entitled to a period of patent term adjustment due to examination delay for the number of days in the period beginning on the day after the date that is three years after the date on which the national stage commenced under 35 U.S.C. §371(b) or (f) (i.e., June 30, 2005). The Office has declined, pursuant to now-current practice, to calculate "B" delay prior to issuance. Nonetheless, to preserve rights, applicants disagree with any USPTO calculation that will differ from that set out below.

Applicants are entitled to a period of patent term adjustment pursuant to 37 CFR §§ 1.702(b) and 1.703(b) due to examination delay for the number of days in the period beginning on the day after the date that is three years after June 30, 2005, when the above-referenced application commenced the national stage under 35 U.S.C. § 371(b) or (f), and ending on the date a patent is issued ("3 Years Delay"). However, pursuant to 37 CFR § 1.703(b)(1), this period does not include the number of days in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. 132(b) was filed (i.e., September 11, 2009) and ending on the date the patent was

issued. Thus, applicants are entitled to a period of patent term adjustment beginning on July 1, 2008 (the day after the date that is three years after June 30, 2005, the date that the national stage commenced), and ending September 11, 2009 (the date the application entered continued prosecution (see 37 CFR § 1.703(b)(1))). This period is 438 days in length.

As indicated in the Notice of Allowance, a patent is projected to issue on May 11, 2010, but may issue earlier or later depending on the circumstances of publication. The period of examination delay will <u>not</u> be extended or reduced depending on the actual date of issuance of a patent from the above-referenced application, because the entire period from September 11, 2009 until the actual issue date will be excluded pursuant to 37 CFR § 1.703(b)(1). Accordingly, the entire period of 3 Years Delay is <u>438 days</u>.

C. Exclusion of Overlapping Delay under 37 CFR § 1.703(f)

Applicants are not entitled to a period of patent term adjustment to the extent that the periods in 37 CFR § 1.702 (14 Month Delay and 3 Years Delay) overlap pursuant to 37 CFR § 1.703(f) ("Overlapping Delay"). Having declined, pursuant to now-current practice, to calculate "B" delay prior to issuance, the Office has not expressly calculated potential overlap. Nonetheless, to preserve rights, applicants disagree with any USPTO calculation that will differ from that set out below.

The Overlapping Delay consists of the period of time when the 14 Month Delay overlaps the 3 Years Delay. See Wyeth v. Kappos, No. 2009-1120 (Fed. Cir. Jan 7, 2010) (stating at p. 8 that "[i]f an A delay occurs on one day and a B delay occurs on a different day, those two days do not 'overlap' under section 154(b)(2)."). The period of 14 Month Delay began on August 31, 2006 and ended on October 22, 2007, when an action under 35 U.S.C. § 132 was mailed. The 3 Years Delay began on July 1, 2008 and ended on September 11, 2009. There is no overlap between these two periods. Applicants have illustrated this graphically in the timeline provided as Exhibit C.

D. Total USPTO delay, 37 CFR § 1.702

Accordingly, applicants submit that the total patent term adjustment under 37 CFR § 1.702 is the sum of the 14 Month Delay and the 3 Years Delay (856 days) less 0 days of overlap, or <u>856 days</u>.

Scrial No. 10/541,195 Page 3 of 4 15429202.1.BUSINESS

E. Exclusion of Applicant Delay under 37 CFR §§ 1.703(f) and 1.704

Applicants are not entitled to a period of patent term adjustment to the extent that they failed to engage in reasonable efforts to conclude prosecution of the application pursuant to 37 CFR §§ 1.703(f) and 1.704 ("Applicant Delay"). Applicants agree with the Office's calculation of Applicant Delay of 159 days as shown in Exhibit B.

F. Total Patent Term Adjustment

Pursuant to 37 CFR § 1.703(f), the total patent term adjustment is 418 days of 14 Month Delay, plus 438 days of 3 Years Delay, minus 0 days of Overlapping Delay, minus 159 days of Applicant Delay, for a total of 697 days.

G. Conclusion

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of 697 days.

Respectfully submitted,

17.

Reg. No. 57,623

Date:	January 15, 2010	Att	
•	***************************************	Stefan M. Miller	

DECHERT LLP Customer No. 37509 Tel: 212,698,3627

Fax: 212.698.3599

Exhibit A



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Advises: COMMISSIONER FOR PATENTS F.O. Box 1450 Alexandra, Viginia 22313-1450 www.nephogov

APPLICATION NO.		FILINO DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/541,195		06/30/2005	Patricia Salvatí	373987-004US (396982)	7746
37509	7590	13/02/2009		EXAMINER	
DECHERT L	LP			TAYAMA	D. SAHAR
P.O. BOX 390460			ARTUNIT	PAPER NUMBER	
MOUNTAIN VIEW, CA 94039-0460				1617	••••••
			DATE MAILED: 11/02/2009		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 259 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 259 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Exhibit B

10/541,195	ALPHA-AMINOAMID	E DERIVATIVES U	ISEFUL AS ANTIMIGRAINE AGENTS 11-10	-2009::15:10:35
Patent Term	Adjustments			
Patent Term A	djustment (PTA) for	Application Num	ber: 10/541,195	
Filing or 371(c) Date:	06-30-2005	USPTO Delay (PTO) Delay (days):	418
Issue Date of I	Patent:	~	Three Years:	-
Pre-Issue Peti	tions (days):	+0	Applicant Delay (APPL) Delay (days):	159
Post-Issue Pe	títions (days):	+0	Total PTA (days):	259
USPTO Adjust	ment(days):	+0	Explanation Of Calculations	
Patent Term /	Adjustment Histor	у		
Date	Contents Descripti	on	PTO(Days)	APPL(Days)
11-02-2009	Mail Notice of Allo	wance		
09-30-2009	Document Verifica	tion		
09-30-2009	Notice of Allowanc	e Data Verificati	on Completed	
09-30-2009	Case Docketed to	Examiner in GAU	ı	
09-28-2009	Examiner's Amend	lment Communic	ation	
09-23-2009	Date Forwarded to	Examiner		
09-23-2009	Date Forwarded to	Examiner		
09-11-2009	Request for Contin	ued Examination	(RCE)	91
09-23-2009	DISPOSAL FOR A if CPA)	RCE/CPA/129 (express abandonment	*
09-11-2009	Request for Extens	sion of Time - Gra	anted	*
09-11-2009	Affidavit(s) (Rule 1	.31 or 132) or Ex	chibit(s) Received	*
09-11-2009	Workflow - Reques	t for RCE - Begin		*
03-12-2009	Mall Final Rejectio	n (PTOL - 326)		*
03-11-2009	Final Rejection			
12-09-2008	Information Disclo	sure Statement o	considered	
12-09-2008	Information Disclo	sure Statement (IDS) Filed	
12-17-2008	Date Forwarded to	Examiner		
12-09-2008	Response after No	n-Final Action		
12-09-2008	Information Disclo	sure Statement (IDS) Filed	
09-18-2008	Mail Non-Final Rej	ection		
09-15-2008	Non-Final Rejectio	n		
05-21-2008	Information Disclo	sure Statement o	considered	
05-21-2008	Reference capture	on IDS		
07-02-2008	Date Forwarded to	Examiner		
05-21-2008	Response after No	n-Final Action		68
05-21-2008	Request for Extens	sion of Time - Gra	anted	*
05-21-2008	Information Disclo	sure Statement (IDS) Filed	*
05-21-2008	Information Disclo	sure Statement ((IDS) Filed	*
03-14-2008	Change in Power o	f Attorney (May I	nclude Associate	#
03-12-2008	Correspondence A	ddress Change		*

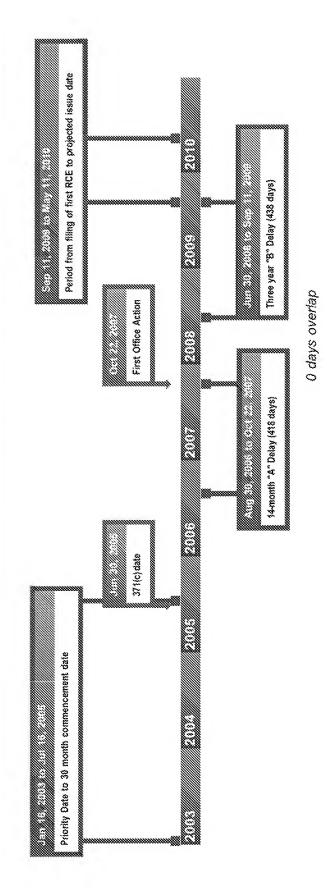
12-15-2007	Electronic Review		#
12-14-2007	Email Notification		*
12-14-2007	Mail Non-Final Rejection		***
12-10-2007	Non-Final Rejection		
06-30-2005	Information Disclosure Statement considered		
12-06-2007	Date Forwarded to Examiner		
11-19-2007	Response to Election / Restriction Filed		
11-27-2007	Case Docketed to Examiner in GAU		
10-24-2007	Electronic Review		
10-23-2007	Email Notification		
10-22-2007	Mail Restriction Requirement	418	
10-16-2007	Requirement for Restriction / Election	11/1	
10-10-2007	Case Docketed to Examiner in GAU	**	
02-07-2006	IFW TSS Processing by Tech Center Complete	11/1	
02-07-2006	Case Docketed to Examiner in GAU	1/4	
06-30-2005	Information Disclosure Statement (IDS) Filed	***	
06-30-2005	Information Disclosure Statement (IDS) Filed	**	
12-30-2005	Cleared by OIPE CSR	*	
12-30-2005	Cleared by OIPE CSR	**	
06-30-2005	371 Completion Date	***	
12-21-2005	Application Dispatched from OIPE		
12-21-2005	Notice of DO/EO Acceptance Mailed		
06-30-2005	Initial Exam Team nn		
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2 of 2 11/10/2009 3:10 PM

# Exhibit C

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Net PTA: 418 days (14-m delay) + 438 days (3-yr delay) - 0 days (overlap) - 159 days (applicant delay) = 697 days